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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,738	06/13/2001	Willis L. Winstrom	POC 01-1-1	4953

23531 7590 12/23/2002

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EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09 820738

Applicant(s)

WINSTROM

Examiner

MSU/ery

Group Art Unit

11

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/21/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 301, 303-310, 322-333 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 301, 303-310, 322-333 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 6
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1616

Examiner appreciates receipt of cancellation of non-elected claims, in response to restriction of 8/12/02.

Claims 301, 303-310, 322 –333 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language can be taken to mean either the g/lb is a dosage of g of drug/Lb of animal, or g of drug/Lb of feed. Please amend. Note that in claims, as 303, for example, one would assume 300g/Lb of granules- however, the specification refers to g/ton of feed. Also, mesh type (claim 309, 310) is not specified and, claim 303=305; 304=306. And finally claim 329 does nothing to the animal with the ~~second~~ solid.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 301, 303-308 are rejected under 35 U.S.C. 102(b) as being anticipated by king 5266347.

The instant method steps: orally administering a prophylactic amount of – medicated supplement-of, dry, uncompacted granules, of uniform size, of antimicrobial sufficient to provide 10g/Lb, is ~~Met~~; King uses fermentation broths (col. 2, line 1-31) as feed supplement, derived from antibiotic organism culture (col. 1, lines 7-14) of the instant invention (amphotericin). The antibiotic biomass is superior (col. 3, lines 7-11), and protects against mycotoxin (col. 4, lines 14-32). The amount used, is 5-20g/ton of

Art Unit: 1616

feed, (col. 3, line 27-40) and can be as high as 2kg/ton of feed. This is the amount of the instant application (p.7).

The formulations are not compressed, since nowhere is compression disclosed. The composition can include soybean meal or flour, or fishmeal (col. 4, lines 5-8, col. 5, lines 22-31; col. 6, line 5) thus, would include the instant claim amount of oil. Rice hulls (lines 5, col.4) or limestone may be used. Moisture content is about 7-8% (col. 5, lines 19-21), thus, inclusive of 6%.

<sup>about</sup>  
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 301, 303-307, 309, 310, 322-333 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Forbes et al, DD 138273.

Translation shows (claims 1 and p.8) veterinary feed premixes of antibiotics obtained by culture fermenting (p.2) and granulated drying, are known. Forbes describes the process (p.4), added antibiotic is admixed (p.5) and drying is at a temperature to preserve activity and would achieve the instant moisture content, as it is the instant temperature. Soybean oil may be added (p.6) pre 200,000,000 units of tylosin produced are sufficient to provide the instant drug dosage to provide prophylactic effects of the medicinal fodder (p. 7).

Additional antibiotics may be added (3<sup>rd</sup> paragraph, p.6), along with added (p.4) tylosin, as would be prepared by the same, fermentation, drying, process as is the known means of providing tylosin. Although/animal dosages are not specified, the thrust of the Forbes invention is to provide tylosin in a form to insure potency for therapeutic known veterinary use (p.2, top). Thus the dosages as instantly claimed, within those of normal veterinary use, are obvious. The granule size is obtained through fluidized bed use, thus, would be of the instant size, in order to provide acceptable taste (p.2) and dust free (p.3, top) protection.

The added and re-added mycelea' are seen as presented in the concept by Forbes; Forbes added already concentrated tylosin to the culture. The added ingredients include other fermentatively recorded biomars (p.6), without limit. It is well within the purview of one in the veterinary arts to adjust the dose as desired, of the medicinal feed premix, to achieve a prophylactic or therapeutic dose of tylosin, as a function of the disease syndrome of concern, desired number of applications, length of time for desired protection, ease of handling, target species, degradation.

Claims 301, 303-310, 322-333 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forbes et al DD 138273 in view of Klothen-4447421.

Forbes (above) provides the instant medicinal premix, but does not address dosage. Klothen does, with the same drug. Tylosin (col. 2, bottom) prepared from the same fermentation processes (col. 3, top) but compacted to achieve the instant granule size (col. 4, lines 5-10). The dosages are, for example of the instant level: 22g/Lb. (Table I).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an effective, stable, medicated feed, to use one of Forbes, as shown able to be provided in therapeutic dose levels, as exemplified by Clothe.


All the critical elements of the instant are disclosed. The amounts of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular pest microbe of interest, reduction of toxicity, cost minimization, palatability, stability animal species to be fed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 305-4556 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy/T.G.D  
December 20, 2002



NEIL S. LEVY  
PRIMARY EXAMINER